DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 23, 2014

LINA Medical ApS
% Ms. Christine E. Nichols RAC
Boston Biomedical Associates
100 Crowley Drive, Suite 216
Marlborough, Massachusetts 01752

Re: K142757
Trade/Device Name: LiNA PowerBlade Plus™ HC
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 24, 2014
Received: September 25, 2014

Dear Ms. Nichols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142757

Device Name
LiNA PowerBlade Plus™ HC

Indications for Use *(Describe)*
The LiNA PowerBlade Plus™ HC is intended for use in open and laparoscopic surgery where grasping, coagulating and transecting is indicated

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5 510(k) Summary

1. Submission Sponsor

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Submission Correspondent

Christine E. Nichols RAC
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100 Crowley Dr., Suite 216
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Date Prepared

September 24, 2014

2. Device Identification

Trade/Proprietary Name:	LiNA PowerBlade Plus™ HC
Common/Usual Name:	electrosurgical, cutting & coagulation & accessories
Classification Name:	Electrosurgical cutting and coagulation device and accessories
Classification Regulation:	21 CFR 878.4400
Product Code:	GEI
Device Class:	Class II
Classification Panel:	General & Plastic Surgery

3. Predicate Device

LiNA PowerBlade Plus™ K132837

4. Device Description

The PowerBlade Plus HC is a sterile 5 mm single use instrument available in one 330mm length version with a 10mm jaw opening. The proposed device is a bipolar forceps device that grasps and coagulates utilizing electrical current. Transecting is done with a mechanical sharp

blade. The LiNA PowerBlade Plus HC includes a rotation wheel on the handle that rotates the grasper jaws at the tip to improve positioning and ergonomics during the surgical procedure. The device is single use ethylene oxide sterilized and is compatible with most standard electrosurgical generators that provide a bipolar outlet. Two types of connectors are provided: the two pin connector is for use with most standard electrosurgical generators with a bipolar outlet, and a 3-pin connector that is attached to the cable of the LiNA PowerBlade Plus HC for use with ValleyLab™ generators with a LigaSure™ outlet. When the 3-pin connector is used, the control button on the hand piece can be used to activate the coagulation. When using the 2-pin connector the coagulation function of the PowerBlade Plus HC is foot pedal controlled.

5. Intended Use

The LiNA PowerBlade Plus HC is intended for use in open and laparoscopic surgery where grasping, coagulating and transecting is indicated.

6. Comparison of Technological Characteristics

This special 510(k) is a modification to the LiNA PowerBlade Plus previously cleared by the FDA via 510(k) K132837. No changes were made to the intended use, indications for use, energy type, materials, sterilization method or fundamental scientific technology. The LiNA PowerBlade Plus HC has the following differences from the predicate: Added hand control activation button for coagulation when device is used with the ValleyLab Generators with a LigaSure outlet, and the addition of a 3 pin connector adapter to allow connection with the ValleyLab Generators that have the LigaSure outlet. The three pin connector adapter can be easily removed from the cable so that the cable is compatible with most ESUs.

Non-Clinical Performance Data

Verification testing was performed as part of design controls to verify functionality of the proposed device and compliance with the same recognized standards as the predicate (IEC60601-1, and IEC60601-2-2).

Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The descriptive information detailed in this submission supports the substantial equivalence of the device.

7. Conclusion Statement of Substantial Equivalence

The differences between the LiNA PowerBlade Plus HC and the predicate LiNA PowerBlade Plus do not raise any new questions regarding its safety and effectiveness. Verification testing and compliance with voluntary recognized standards, demonstrate that the LiNA PowerBlade Plus is substantially equivalent to the predicate device LiNA PowerBlade Plus in terms of design, components, principals of operation, sterilization, performance characteristics, and intended use. The LiNA PowerBlade Plus, as designed is determined to be substantially equivalent to the referenced predicate device.